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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,792	03/30/2004	Georges Belfort	18001/5062 (RPI-806)	4213

7590 08/25/2006

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EXAMINER	
BAUGHMAN, MOLLY E	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/812,792	BELFORT ET AL.	
	Examiner	Art Unit	
	Molly E. Baughman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/30/04*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 11 in part, 12-17, 20-37, 38 in part, 39-44, 47-53, 54 in part, and 55-60, drawn to a method of recovering a target entity from a polydisperse liquid, wherein the target entity is selected from a group consisting of: a protein, polypeptide, amino acid, and antibody, and wherein the polydisperse liquid is milk produced by a transgenic animal, classified in class 435, subclass 326 or class 210, subclass 905.

II. Claims 1-10, 11 in part, 12-15, 18-19, 20-37, 38 in part, 39-42, 45-53, 54 in part, 55-58, and 61-62, drawn to a method of recovering a target entity from a polydisperse liquid, wherein the target entity is selected from a group consisting of: a protein, polypeptide, amino acid, and antibody, and wherein the polydisperse liquid is cell culture fluid from transgenic plants, classified in class 530, subclass 370.

III. Claims 1-10, 11 in part, 16-17, 20-37, 38 in part, 43-44, 47-53, 54 in part, and 59-60, drawn to a method of recovering a target entity from a polydisperse liquid, wherein the target entity is selected from a group consisting of: a colloid, mycoplasm, endotoxin, and carbohydrate, and wherein the polydisperse liquid is milk produced by a transgenic animal, classified in class 127, subclass 40.

IV. Claims 1-10, 11 in part, 18-19, 20-37, 38 in part, 45-53, 54 in part, and 61-62, drawn to a method of recovering a target entity from a polydisperse liquid, wherein the target entity is selected from a group consisting of: a colloid, mycoplasm, endotoxin, and carbohydrate, and wherein the polydisperse liquid is cell culture fluid from transgenic plants, classified in class 536, subclass 128.

V. Claims 1-10, 11 in part, 16-17, 20-37, 38 in part, 43-44, 47-53, 54 in part, and 59-60, drawn to drawn to a method of recovering a target entity from a polydisperse liquid, wherein the target entity is selected from a group consisting of: RNA and DNA, and wherein the polydisperse liquid is milk produced by a transgenic animal, classified in class 435, subclass 144.

VI. Claims 1-10, 11 in part, 18-19, 20-37, 38 in part, 45-53, 54 in part, and 61-62, drawn to a method of recovering a target entity from a polydisperse liquid, wherein the target entity is selected from a group consisting of: DNA and RNA, and wherein the polydisperse liquid is cell culture fluid from transgenic plants, classified in class 536, subclass 236.

VII. Claims 1-10, 11 in part, 16-17, 20-37, 38 in part, 43-44, 47-53, 54 in part, and 59-60, drawn to drawn to a method of recovering a target entity from a polydisperse liquid, wherein the target entity is a virus, and wherein the polydisperse liquid is milk produced by a transgenic animal, classified in class 435, subclass 239.

VIII. Claims 1-10, 11 in part, 18-19, 20-37, 38 in part, 45-53, 54 in part, and 61-62, drawn to a method of recovering a target entity from a polydisperse liquid, wherein the target entity is a virus, and wherein the polydisperse liquid is cell culture fluid from transgenic plants, classified in class 435, subclass 235.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions (I, II), (III, IV), (V, VI), and (VII, VIII) are directed to related method of recovering a target entity from a polydisperse liquid. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions are drawn to different target entities, which due to their differences in structure and size, require different methods of preparation and purification. Various steps of the instant method require attention to the target entities' isoelectric pH, which varies depending on the target entity. As stated on page 6 of the specification, "distinctive features of the UF step are the optimization of ionic strength, pH, and permeation flux to achieve protein separation at a pH different from the pI of any of the proteins involved by using concentration polarization and the correct amount of charge shielding." As such, special attention is required for optimizing the method for each target entity to achieve a successful filtration. For example, Inventions I and II are drawn to target entities

consisting of a protein, polypeptide, amino acid, and antibody, which are completely different in terms of structure and function than the target entities of Inventions III and IV (colloid, mycoplasm, endotoxin, and carbohydrate). Carbohydrates are more hydrophobic in nature, consist of carbon, hydrogen and oxygen, and functionally store energy and provide structural support. On the contrary, proteins are more hydrophilic, are made up of secondary structures of polypeptides, and among other functions, provide signaling reactions through their binding interactions with molecules in the body. Based on their differing sizes, structures and functions, one of skill in the art would expect carbohydrates and proteins, and likewise, each target entity group, to react differently in a given set of reagents, conditions. This would require different methods for each target entity, and therefore, restriction is deemed proper.

Searching the inventions of Groups (I, II), (III, IV), (V, VI), and (VII, VIII) together would impose serious search burden. The inventions of Groups (I, II), (III, IV), (V, VI), and (VII, VIII) have a separate status in the art as shown by their different classifications.

In the instant case, the search of purification, or filtration (i.e. recovering) of proteins, polypeptides, amino acids, colloid, mycoplasm, endotoxin, virus, carbohydrate, RNA, DNA, and antibodies are not coextensive. For example, the existence of prior art to the instant method could be devoted solely to isolating specific antibodies against HIV, which would not have described isolating the virus as well. Searching, therefore is not coextensive. In addition, the search requires an extensive analysis of the art retrieved in the structure and function of each target entity, providing insight to their individual isoelectric pH, which is critical to the invention and will require an in-depth analysis of technical literature. As such, it would be burdensome to search the inventions of target entity groups together.

3. Inventions (I, III, V, VII) and (II, IV, VI, VIII) are directed to related method of recovering a target entity from a polydisperse liquid. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Inventions (I, III, V, VII) are drawn to recovering a target entity from milk produced by a transgenic animal and Inventions (II, IV, VI, VIII) are drawn to recovering a target entity from cell culture fluid from transgenic plant cells. In general, milk from an animal and cell culture fluid from plant cells contain numerous different solutes, molecules, fluids, etc. which would require different methods of preparation and filtration. For example, milk from a cow consists of fat, lactose, casein proteins, enzymes, minerals, vitamins, hormones, water and furthermore, its composition varies because of diet, breed, genetics, mastitis, stage of lactation of the cow, as well as environmental conditions.

Searching the inventions of Groups (I, III, V, VII) and (II, IV, VI, VIII) together would impose serious search burden. The inventions of Groups (I, III, V, VII) and (II, IV, VI, VIII) have a separate status in the art as shown by their different classifications.

In the instant case, the search of purification, or filtration (i.e. recovering) of milk from a transgenic animal and cell culture fluid from a transgenic plant are not coextensive. For example, prior art teaching the instant method, directed to purifying cell culture fluid from a transgenic plant, in preparation for freeze-drying the liquid containing the target entity, would not have described filtering and purifying milk from a

transgenic animal as well. Searching, therefore is not coextensive. In addition, the search requires an extensive analysis of the art retrieved in milk from transgenic animals and furthermore, cell culture fluid from transgenic plants, containing different conditions and compositions for each species of plant as claimed and each species of animal as claimed, and will require an in-depth analysis of technical literature. As such, it would be burdensome to search the inventions of polydisperse liquid groups together.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Molly E. Baughman whose telephone number is 571-272-4434. The examiner can normally be reached on Monday-Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Molly E Baughman
Examiner
Art Unit 1637 MEB 8/18/06

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
8/21/06